



# Managing information overload

**Companies know they need regulatory information management. What they don't always know is where to start and how to weave this vital capability across the enterprise's diverse and discrete technology applications.**

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**D**ata is information waiting to happen, but today's global pharmaceutical companies are riddled with data—so much that their numerous functions and disparate systems struggle to know what to do with all of it. Worse still, these data are usually disconnected, duplicated and, all too often, inaccurate.

Data is generated by the day-to-day activities that take place in each department. Regulatory operations personnel, for example, produce documents, develop submissions and file them in for approval. However, a submission begins long before the documents themselves are created. The process commences with the generation of concepts that get encapsulated into documents, which ultimately form the regulatory submission. Submissions become part of a portfolio across multiple nations, with concomitant licences that must be managed. In most cases, data gathering is managed locally, with regulatory departments drawing on the minimal amount of information needed to adhere to requirements or to track commitments. What is often missing is the ability to aggregate information across the enterprise so that it can be used to conduct more predictive work, such as project planning across the portfolio, resource planning, and pre- and post-marketing activities. In so doing, companies can manage their activities more holistically.

Other industries have been quicker to grasp the importance of information management. Perhaps one of the best examples is the automobile industry; for example, when problems arise with a particular model, the manufacturer can respond quickly by linking

manufacturing information with warranty information. When a manufacturer spots a trend, such as a faulty part, it can both ensure that its dealers are ready with the new parts and send out relevant recall letters, thereby helping to minimise any escalation in cost.

## Information overload

Pharmaceutical companies are aware of the data they generate and capture. According to a survey by the consulting group Ovum (1), the pharmaceutical industry is ahead of other industries when it comes to adopting enterprise applications, such as customer relationship management (CRM) and enterprise resource planning (ERP) solutions, but lags behind with business intelligence solutions such as regulatory tracking and management systems that can harness data productively.

Poor information management can create a bottleneck for companies on multiple levels, as well as add unnecessary cost burdens. Take the cost of storage, for example; failing to manage data results in the retention of redundant information and records, which occupy storage space within a system. Then there's the time cost associated with chasing information needed to meet regulatory requirements or to make a business or strategic decision.

One particular problem that company leaders have identified is the use of multiple terms or definitions to describe one thing because it may mean that information about a product exists within several systems, with each system having its own definition.

Consolidating this information can pose challenges.

Information management aims to reduce the time it takes for people to locate relevant content and enable them to make confident business decisions based on informative data. From a strategic point of view, good information management is what stands between sluggish response times and streamlined business practices. All of a company's information should be connected. Ideally, submissions flow into licensure, which then flows into the portfolio.

Tracking resources via project planning, the authoring process, the submission process and, ultimately, approval makes it possible to form a bigger picture of how resources are being managed and where they might best be directed. Companies can use this informational picture for resource prediction across multiple products and countries. For instance, good information management can concurrently track license renewals, products that are coming to the end of their patent life, new products entering the market and the state of current R&D projects. This information can help answer questions such as:

- Is it in the company's interest to continue marketing a particular product?
- Should the company look for a partner?
- Are there opportunities for a product extension and what would the market potential for additional indications be?

Good regulatory information management results in a detailed and analytic understanding of all the components pertinent to a particular product. If a problem arises somewhere along the line, it also enables the company to quickly determine what the problem is and then decide on a resolution.

### From bottom to top

Successful information management requires a technology solution that encompasses all enterprise applications, including document management, ERP and customer management. Ovum analyst Sarah Burnett describes the complete, multi-layered enterprise package as the

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information management stack (1):

- The information stack begins at the infrastructure level, which comprises both internal applications, such as file systems, databases, and archiving, and external sources of data, which may encompass cloud deployments such as software services, RSS feeds and web-generated information.
- Next comes data management, life cycle management, the retirement of old data that is no longer required, archiving and records management. Often, companies have data or reports that, while not active, need to be accessible in the near term. Even though some solutions allow for this type of storage, it's also important that companies learn how to classify information to simplify the task of finding it. Furthermore, there's a need to standardise the way information is classified, as the use of different terms negates the value of data storage. Another crucial aspect of data management is metadata management. What that means is that more time needs to be spent resolving issues around data definitions and improving data quality because having good and consistent data from the outset will allow companies to produce better quality reports and analysis.

- The third layer in the information management technology stack comprises data extraction and integration. First, there's data warehousing or data consolidation, which deals with longer-term data cycles. This system is most appropriate when there are definitional discrepancies or when a lot of data cleansing is required. Data warehousing or data consolidation is valuable in so far as it lets personnel conduct multidimensional analyses. If, for example, a number of issues have arisen during drug development, business leaders can use the data to analyse the value and cost of the project.

Another technology that fits into the extraction and integration layer is data federation, or data virtualisation, whereby a department or business leader might grab snippets of information from different systems for quick access and analysis. This technology

is most applicable for small quantities of data that don't require substantial transformation or cleansing. According to Burnett, data virtualisation enables users to quickly access data that is pertinent to their particular requirements. Master data management, which gives users a single view of an important part of the business, such as a product or a customer, also fits into this layer. One example might be filling in missing pieces of data in a record or removing errors from a record. The final part of the extraction/integration stack is service-oriented architecture or data services. This is another way of breaking data into components that can be reused at various points throughout the organisation.

- Information services is second from the top of the stack. For most users, this level is where the more familiar tools and applications such as search, retrieval, audit and forecast are found.
- At the top of the stack is delivery, which focuses on making information easier for the user to digest and understand. Delivery allows information to be synthesised for a particular user, such as financial, project management and development or scientific research.

### Conclusion

Regulatory information management involves far more than just tracking submissions. The processes and technologies used to enable successful regulatory information management help companies to consolidate their disparate systems and produce meaningful, holistic information that leads to better decision-making. The starting point is managing and structuring the data in a clear and consistent manner. Only by having clean, consistent and reliable data is it possible to build a broad picture of how an organisation's resources are currently being used and how they can be maximised in the future. [PTE](#)

### References

1. S. Burnett, "The Information Management Imperative"(presentation given in London (UK), September 2010).